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PRE-APPEAL BRIEF REQUEST FOR REVIEWDocket Number (Optional)
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on March 21, 2006Signature Christine KierzekTyped or printed
name Christine KierzekApplication Number
10/045,937Filed
10/19/2001First Named Inventor
David J. Beebe et al.Art Unit
1743Examiner
Lyle Alexander

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

- ☒ attorney or agent of record.
Registration number 36,020

- ☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34. _____

SignaturePeter C. Stomma
Typed or printed name414.225.9755
Telephone number3/21/06
DateNOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

- ☒ *Total of 1 forms are submitted.

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

The Examiner has rejected claims 10, 13-29 and 31-36 under 35 U.S.C. § 102(e) as being clearly anticipated by McDewitt et al., United States Patent Application No. 2003/0064422. In addition, the Examiner has rejected claims 10, 17-21, 24-29 and 33-36 under 35 U.S.C. § 102(b) as being clearly anticipated by Tiru et al., US Patent No. 4,149, 852 and has rejected claims 10, 13-29 and 31-36 under 35 U.S.C. § 103(a) as being unpatentable over Beebe et al., U.S. Patent No. 6,488,872. Applicant believes that these rejections by the examiner constitute clear error, and as such, review and reversal of the Examiner's rejections are respectfully requested.

Referring to claim 10, a method is defined for monitoring the environment within a microfluidic device. The method includes the steps of immobilizing a monitor structure in a channel of a microfluidic device and passing fluid over the monitor structure. The monitor structure generates a visual display independent of the size of the monitor structure in response to a parameter of the fluid having a predetermined value. The monitored structure is immobilized in the channel by performing the additional steps of mixing a dye in a pre-polymer mixture and providing the same as a pregel; injecting the pregel in the channel of the microfluidic device; and polymerizing the pregel in the channel to form the monitor structure. As hereinafter described, the cited references do not show or suggest the methodology defined in claim 10 of the present application.

The McDevitt '422 application discloses a method and system for selecting and transmitting chemical information. Referring to Fig. 3 of the '422 application, the system includes a silicon wafer having a plurality of spaced cavities 230 formed therein. Particles 235 are positioned at the bottom of corresponding cavities 230 using e.g., a micromanipulator. Referring to paragraphs 0123 and 0127 of the '422 application, it is contemplated for the particles to swell in response to contact with a fluid. Alternatively, referring to paragraph 0144, it is contemplated to bind a receptor to a polymer resin created particle wherein the receptor includes an indicator that generates a modulated signal in response to the binding an analyte to the particle.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Clearly, the '422 application does not disclose each and every step of independent claim 10. More specifically, even assuming that binding of the receptor to the particles constitutes "mixing" as provided for in claim 10, the '422 application does not contemplate "mixing a dye into a pre-polymer mixture and providing the same as a pregel." Further, the '422 application clearly does not suggesting injecting the *pregel* into a channel of a microfluidic device or *polymerizing the pregel in the channel* to form a monitor structure. The suggestion of polymering a pregel with a channel of a microfluidic device is entirely absent from the '422 application. Consequently, it is believed that the '422 application does not disclose each and every element as set forth the claim 10. Hence, it is believed the examiner's rejection of claim 10 under 35 U.S.C. § 102(e) is clear error and such rejection should be withdrawn.

The Tiru et al. '852 patent discloses a pH indicator composition having controlled change of color at selected sub-freezing temperatures. The composition includes a pH indicator and a control agent added to a buffer solution. When frozen, the composition is useful in a color change thermometer. For example, referring to column 10, lines 47-51 of the '852 patent, it is contemplated to fill a chamber or capsule with the thermochromatic composition. The chamber or capsule may be affixed to a product and allow a user to determined if the temperature of the product is above or below a predetermined value. It is noted that, unlike claim 10, the '852 patent does not disclose a microfluidic device; a pre-polymer mixture; the mixing of a dye into the pre-polymer mixture and providing the same as a pregel; injecting the pregel into a channel of the microfluidic device; or polymerizing the pregel to form a monitor structure.

As is known, polymerization is a chemical process that combines several monomers to form a polymer or polymeric compound. On the other hand, the '852 patent merely discloses the mixing a pH indicator in a solution. Freezing is not polymerization. As such, since the '852 patent does not disclose each and every element/step as set forth the claim 10, it is believed the examiner's rejection of claim 10 under 35 U.S.C. § 102(e) is clear error and such rejection should be withdrawn.

The Beebe et al. '872 patent is directed to a method of fabricating a microfluidic device. Referring to Figs. 1a-1b of the '872 patent, a detection device is provided for detecting a component in the biological fluid or other liquid media is provided. The device 100 contains a responsive hydrogel 102 in microchannel 104. Responsive hydrogel 102 contracts upon exposure to an analyte of interest, thereby allowing component A in a microchannel 108 to flow

to a chamber 106 and mix with a component B in order to produce a detectable change, for example, a color change in chamber 106. The color change provides a macroscale response to a microscale event, i.e., contact of the analyte of interest with responsive hydrogel 102.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

During prosecution of the present application, the Examiner suggested that page 8, line 18 + of the Beebe et al., '872 patent teaches a pH sensitive polymer mixture hydrogel. As such, in the Examiner's opinion, such a pH sensitive hydrogel reads on the claimed subject matter. However, the '872 patent merely disclosed a device wherein a hydrogel sensor actuator changes size in response to a change in pH. There is no suggestion or teaching in the '872 patent to mix a dye into a pre-polymer mixture to form a pregel, inject that pregel into a channel of a microfluidic device, and to polymerize the mixture to form a monitor structure. More specifically, there is nothing in the '872 patent that shows or suggests immobilizing a dye within a hydrogel. The suggestion of such a methodology is entirely absent from the cited references. As heretofore described, the '872 patent merely disclosed a device wherein a hydrogel sensor actuator changes size in response to a change in pH.

Since the cited '872 patent fails to teach or suggest all the claim limitations of claim 10, it is believed that the examiner has failed to establish a *prima facie* case of obviousness. As such, the examiner's rejection of claim 10 under 35 U.S.C. § 103(a) over the '872 patent is clear error and such rejection should be withdrawn.

In view of foregoing, Applicant believes that the examiner's rejection of claim 10 constitutes clear error, and as such, reversal of the Examiner's rejection is respectfully requested. Claims 13-17 and 28 depend either directly or indirectly from independent claim 10 and further define a microfluidic device not shown or suggested in the art. It is believed that claims 13-17

and 28 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Referring to claim 18, a method is provided for monitoring the environment within the microfluidic device. The method includes the steps of mixing a dye in a prepolymer mixture and providing the same as a pregel. Thereafter, the pregel is injected in the channel within a microfluidic device and polymerized in the channel to form a monitor structure. The fluid is passed over the monitor structure in the channel such that the dye changes color in response to a parameter of the fluid having a predetermined value.

As heretofore described with respect to claim 10, the '442 application and the '852 patent do not disclose the steps of mixing a dye into a prepolymer mixture and injecting the prepolymer mixture to a channel of a microfluidic device, where the prepolymer mixture is polymerized. As previously noted, the '422 application do not disclose polymerizing a prepolymer mixture within a channel of microfluidic device and the '852 patent does not disclose a pre-polymer mixture or polymerization of such a mixture as required by claim 18. Further, while the Beebe et al. '872 patent discloses a hydrogel that expands and contracts in response to exposure to a fluid having a predetermined parameter such as the value of pH, the '872 patent does not teach or contemplate mixing a dye in a prepolymer mixture and providing the same as a pregel; injecting the pregel into a channel of the microfluidic device; or polymerizing the pregel in the channel to form a monitor structure, as required by claim 18. Consequently, Applicant believes that the examiner's rejection of claim 18 constitutes clear error, and as such, reversal of the Examiner's rejection is respectfully requested. Claims 19-27 depend either directly or indirectly from independent claim 18 and further define a method not shown or suggested in the prior art. It is believed that claims 19-27 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Referring to claim 29, a microfluidic device is defined that provides a visual display in response to a change in a predetermined parameter of the fluid flowing therethrough. The microfluidic device includes a body defining a channel for accommodating the flow of fluid therethrough. A monitor structure is retained in the channel of the body at a user-desired position within the flow of fluid. The monitor structure has a color. An immobilized dye is entrapped within the monitor structure. The dye changes the color of the monitor structure in response to a change in the predetermined parameter of the fluid. The monitor structure includes

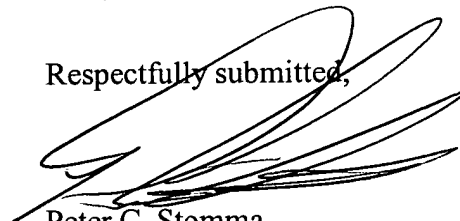
a polymerized mixture. In addition, the immobilized dye is a first color in response to the predetermined parameter of the fluid having a first value and a second color in response to the predetermined parameter of the fluid having a second value.

As heretofore described, nothing in the cited references shows or suggests providing a monitor structure within a channel of a microfluidic device wherein the monitor structure includes an immobilized dye entrapped therein; or the immobilized dye is entrapped within a monitor structure that includes a polymerized mixture. As previously noted, the '422 application merely discloses the binding of a receptor that senses the changes in pH in a fluid sample to a polymer resin particle. The '852 patent does not disclose a polymerized mixture or entrapping a dye within the polymerized mixture as required by claim 29. Finally, while it is noted that the Beebe et al. '872 patent discloses a hydrogel that expands and contracts in response to exposure to a fluid having a predetermined parameter such as the value of pH, the '872 patent does not teach or contemplate entrapping a dye within a polymerized mixture.

In view of the foregoing, Applicant believes that the examiner's rejection of claim 29 constitutes clear error, and as such, reversal of the Examiner's rejection is respectfully requested. Claims 31-36 depend either directly or indirectly from independent claim 29 and further define a microfluidic device not shown or suggested in the prior art. It is believed that claims 31-36 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Applicant believes that the examiner's rejection of claims 10, 13-29 and 31-36 constitutes clear error, and as such, reversal of the Examiner's rejection is respectfully requested.

Respectfully submitted,



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